

Remarks

Claims 1-73 are pending. Claims 16, 17, 30 and 73 have been amended. Claims 63-67 have been withdrawn from consideration as being drawn to a non-elected invention.

Response to Restriction Requirement

In the Office Action mailed June 23, 2004, the claims were divided into two groups, Group I, claims 1-62 and 68-73, drawn to a method of amplifying mRNA, classified in 435, subclass 6; and Group II, claims 63-67, drawn to a kit and composition for amplifying mRNA, classified in class 435, subclass 6. A provisional election of the claims of Group I was made in a telephone conversation with the Examiner on May 4, 2004. As required, Applicants now affirm the election of the claims of Group I.

Response to Claim Objections

1. Claim 30 was objected to because in claim 30 “phytoerythrin” was misspelled.

Claims 30 and 73 have been amended herein by substituting the word “phycoerythrin” for “phytoerythrin”. Support for “phycoerythrin” can be found at least on page 3, lines 24-25, where Applicants provide: “The RCA product is then detected with anti-BrdU-antibody conjugated to a fluorophore, such as phycoerythrin (PE).” Further support can be found on page 77, lines 15-16 where Applicants provide: “After washing, the RCA product is detected with anti-BrdU antibody that is conjugated to a fluorophore, such as phycoerythrin (PE).”

By amending the claims, Applicants submit that the proper spelling of “phycoerythrin” has been incorporated in the claims and respectfully request withdrawal of the objection.

2. Claim 37 was objected to because claim 37 allegedly is a duplicate of claim 2. Applicants respectfully traverse this objection.

The present objection is based on a misinterpretation of claims 2 and 37. Claim 37 does not duplicate claim 2. Claim 2 reads in part: “The method of claim 1 wherein the capture tag associates with the RT primer”, whereas claim 37 reads in part: “The method of claim 1 wherein the RT primer comprises a capture tag.” In claim 2, there is an association between the capture tag and the RT primer, thus there is an interaction between two different substrates. This is different from claim 37, where the capture tag is a part of the RT primer, therefore a separate

interaction is not required, as in claim 2. To the extent that the subject matter of claims 2 and 37 is the same or similar, Applicants note that claims 2 and 37 are not identically worded and applicants are allowed to restate what they consider to be their invention in a reasonable number of ways. MPEP § 706.03(k). Applicants submit that for at least these reasons claim 37 is not a duplicate of claim 2. Accordingly, Applicants respectfully request withdrawal of the objection.

Rejection Under 35 U.S.C. § 112, second paragraph

Claims 16-17 were rejected under 35 U.S.C. § 112, second paragraph, for lacking sufficient antecedent basis. Specifically, the Office Action alleges “Claims 16-17 recites the limitation ‘half probe’ in lines 2 and 3 of the claims respectively. There is insufficient antecedent basis for this limitation in the claim.”

Applicants first note that it is not clear in what way the term “half probes” lacks antecedent basis in the claims. The term is properly introduced in claim 16 in the phrase “one or more half probes”. There is no indication that this phrase is or was intended to refer to a previously introduced component. Accordingly, the basis of this rejection is not clear and withdrawal of the rejection is respectfully requested.

Notwithstanding this, Applicants amend claims 16 and 17 herein by substituting the word “sub-probe” or “sub-probes” for “half probe” or “half probes”, respectively. Support for “sub-probes” can be found at least on page 9, line 27, to page 10, line 9 and page 26, lines 4-29, where Applicants describe sub-probes and their use. Applicants submit that the term “sub-probes” is properly introduced in claim 16 and that the term has proper antecedent basis in claim 17, and therefore claims 16 and 17 satisfy the requirements of 35 U.S.C. § 112, second paragraph.

Rejection Under 35 U.S.C. § 102

Claims 1, 4-15, 18-29, 31-36, 40-45, 62, 68, 70-72 were rejected under 35 U.S.C. § 102(a) as being anticipated by Alsmadi et al. (U.S. Pat. No. 6,573,051 B2). Applicants respectfully traverse this rejection.

The present rejection is based on misinterpretations of Alsmadi et al. and of the claimed method. Alsmadi et al. does not disclose what is alleged in the Office Action and does not disclose what is presently claimed. As a result, Alsmadi et al. fails to disclose every feature of

the present claims. This error renders the rejection legally flawed with the result that the Office Action fails to establish a prima facie case of anticipation. In making a rejection under 35 U.S.C. § 102, the Patent Office is burdened with establishing that the cited art teaches each and every limitation of the claims. The present rejection does not meet this burden.

Alsmadi et al. discloses compositions and methods for reducing or eliminating generation of unwanted, undesirable, or non-specific amplification products in nucleic acid amplification reactions. The method disclosed by Alsmadi et al. involves bringing open circle probes (OCP) into contact with a target sequence which induces circularization of the OCP. Once the OCP becomes circularized, it is then amplified via rolling circle replication. According to Alsmadi et al., OCPs are linear single-stranded DNA molecules that contain different portions that have specific functions which make the OCP useful for rolling circle amplification or ligation-mediated RCA (LM-RCA). See col. 7, ll. 66-67 and col. 8, ll. 53-54. One of the optional portions is referred to as the address tag portion, which is part of either the target probe portion or the spacer region of the OCP. See col. 12, ll. 13-14. When the OCP is ligated and replicated, the address tag portion, when incorporated in the OCP, is copied into the replicated DNA copy referred to as tandem sequences DNA (TS-DNA). The address tag portion then a part of the TS-DNA has a sequence complementary to the sequence of an address probe that, upon binding, can immobilize the TS-DNA. See col. 12, ll. 16-20. As such, Alsmadi et al. teaches hybridization of an address probe to TS-DNA. Alsmadi et al. fails to disclose association of target cDNA with either a capture probe or an address probe.

Applicants claim a method of amplifying messenger RNA that involves, *inter alia*, association of an RT primer with a nucleic acid sample and reverse transcribing to produce cDNA. Significantly, however, the reverse transcribed cDNA is hybridized with a set of capture probes. See step (b) of claim 1; step (b) of claim 62; line 7 of claim 68; lines 5-6 of claim 70; line 7 of claim 71; and line 6 of claim 72. Capture probes and their use generally are described in the present application on page 34, lines 5-18; page 5, lines 22-28; from page 7, line 25 through page 8, line 5, and page 7, lines 11-15 of the application.

Applicants submit that Alsmadi et al. does not disclose any step of hybridizing a capture probe to cDNA strands produced by reverse transcription of a nucleic acid sample as required by the present claims. See step (b) of claim 1; step (b) of claim 62; line 7 of claim 68; lines 5-6 of claim 70; line 7 of claim 71; and line 6 of claim 72. At least because Alsmadi et al. fails to disclose hybridizing a capture probe to the cDNA strands produced by reverse transcription of the nucleic acid sample, Alsmadi et al. fails to disclose every feature of the claimed method. Accordingly, Alsmadi et al. fails to anticipate claims 1, 4-15, 18-29, 31-36, 40-45, 62, 68, 70-72.

Response to Specific Bases of the Rejection

1. The Office Action alleges (page 4, line 6) that Alsmadi et al. teaches “hybridizing the cDNA strands to a set of capture probes,” citing column 12, lines 13-22 of Alsmadi et al., which describes “address tag portions” of open circle probes. Such a comparison is misplaced and incorrect as address tags and capture probes are not equivalents nor are they used in Alsmadi et al. in the way the claims require.

In the claimed method, the cDNA strands produced from reverse transcribing of the RNA in a nucleic acid sample are mixed with a set of capture probes under conditions that promote hybridization of the cDNA strands to the capture probes. That is, the claims require that the capture probes hybridize with the target nucleic acid. See step (b) of claim 1; step (b) of claim 62; line 7 of claim 68; lines 5-6 of claim 70; line 7 of claim 71; and line 6 of claim 72; see also page 34, lines 5-18; page 5, lines 22-28; page 7, line 25 - page 8, line 5; and page 7, lines 11-15. The cited passage of Alsmadi et al. does not disclose the use of a capture probe at all, much less a capture probe that associates with the target nucleic acid. Rather, in the cited passage Alsmadi et al. discloses what they refer to as an address tag that is part of an OCP and has a sequence matching what they refer to as an address probe. In Alsmadi et al., the OCP binds to the target nucleic acid, the probe circularizes to allow for later replication of the circularized OCP via rolling circle replication (“RCA”). The address tag portion of the OCP, since it is part of the OCP, is amplified during RCA. RCA results in tandem sequence DNA (TS-DNA) having address tag sequences that are complementary to the complementary portion of the address

probes. Address probes can then be hybridized to the TS-DNA. For example, Alsmadi et al. states:

Address probes immobilized on a solid-state substrate allow capture of the products of RCA and RCT on a solid-state detector. Such capture provides a convenient means of washing away reaction components that might interfere with subsequent detection steps. By attaching different address probes to different regions of a solid-state detector, different RCA or RCT products can be captured at different, and therefore diagnostic, locations on the solid-state detector.

Column 28, lines 4-12 (emphasis added).

This is different from the claimed hybridization of the target cDNA with a set of capture probes. Thus, Alsmadi et al. fails to disclose the claimed capture probes or their claimed hybridization to the target cDNA. Accordingly, Alsmadi et al. fails to describe every feature of claims 1, 4-15, 18-29, 31-36, 40-45, 62, 68, 70-72.

Applicants also note that the rejection fails to address the discrepancy between the claimed hybridization of the target cDNA with a set of capture probes and the use of address probes to hybridize to TS-DNA referred to in Alsmadi et al. Because the relevance of the address probes of Alsmadi et al. to the claimed hybridization of the target cDNA with a set of capture probes step is not provided in the rejection and because the use of address probes to hybridize to TS-DNA of Alsmadi et al. are not in fact relevant to the claimed hybridization of the target cDNA with a set of capture probes step, the use of address probes in Alsmadi et al. do not support a prima facie case of anticipation. Simply put, a prima facie case of anticipation cannot be established by an unsupported assertion that a step in the cited art is the same as a claimed step, especially when the two steps are clearly different and unrelated.

For at least these reasons, Alsmadi et al. fails to anticipate claims 1, 4-15, 18-29, 31-36, 40-45, 62, 68, 70-72.

2. The Office Action also alleges (page 4, lines 7-10) that Alsmadi et al. teaches “mixing one or more rolling circle replication primers with the cDNA strands under conditions that promote association of the cDNA strands with the rolling circle replication primers, wherein the rolling circle replication primers each comprise a capture tag, and wherein association occurs via

the capture tag.” It is not clear where Alsmadi et al. is alleged to disclose this because the Office Action does not provide an immediate citation to Alsmadi et al. However, after the next sentence in the Office Action, the Office Action cites col. 13, lines 61-67; col.14, lines 1-9, 11-17; and col. 35, lines 35-39. The cited passages do not disclose association of the rolling circle replication primer as required by the claims.

The Office Action first cites from column 13, line 61, to column 14, line 17. This passage describes (1) tandem sequence DNA, which is the product of rolling circle replication of an amplification target circle; (2) specific sequences represented in tandem sequence DNA, including "primer sequences" (which match the sequence of the rolling circle replication primer used to produce the tandem sequence DNA); (3) the fact that these specific sequences correspond to specific portions of the amplification target circle that served as the template for the tandem sequence DNA; and (4) that rolling circle replication primers have sequence complementary to the primer complement portion of an amplification target circle. Nothing in this passage suggests that the rolling circle replication primer is to be associated with cDNA or any target DNA. Rather, this passage describes the relationship between rolling circle replication primers and amplification target circles or tandem sequence DNA, not between rolling circle replication primers and cDNA or target DNA.

The Office Action also cites column 35, lines 35-59. This passage describes (1) detection of RNA; and (2) rolling circle replication of amplification target circles by rolling circle replication to form tandem sequence DNA where rolling circle replication is primed by a rolling circle replication primer that is complementary to the primer complement portion of an amplification target circle. Nothing in this passage suggests that the rolling circle replication primer is to be associated with cDNA or any target DNA. Rather, this passage describes the use of rolling circle replication primers to prime rolling circle amplification of amplification target circles to form tandem sequence DNA.

Thus, the passages of Alsmadi et al. cited in the Office Action do not disclose the claim feature purportedly taught (mixing one or more rolling circle replication primers with the cDNA strands under conditions that promote association of the cDNA strands with the rolling circle

replication primers, wherein the rolling circle replication primers each comprise a capture tag, and wherein association occurs via the capture tag). For at least this reason, Alsmadi et al. fails to disclose every feature of the rejected claims. Accordingly, Alsmadi et al. fails to anticipate claims 1, 4-15, 18-29, 31-36, 40-45, 62, 68, and 70-72.

3. The Office Action also alleges (page 4, lines 23-24) that Alsmadi et al. teaches the ends of the capture probes are extendable when a cDNA strand is hybridized to a capture probe. The Office Action relies on col. 40, lines 13-16 of Alsmadi et al. to support this allegation.

The cited portion of Alsmadi et al. provides: “The combinations of labels establish a code for identifying different detection probes and, by extension, different target molecules to which those detection probes are associated with.” Col. 40, lines 13-16. In other words, the combinations of labels establish a code for identifying different target molecules that are associated with different detection probes. The use of the word “extension” in this passage in Alsmadi et al. has nothing to do with extension of probes by nucleic acid synthesis, which is what the word “extendable” in present claims 13-15 refers to. See claim 15. Thus, the cited passage in Alsmadi et al does not disclose the claimed feature purportedly taught (capture probes extendable by polymerase). For at least this reason, Alsmadi et al. fails to disclose every feature of the claims. Accordingly, Alsmadi et al. fails to anticipate claims 1, 4-15, 18-29, 31-36, 40-45, 62, 68, and 70-72.

4. The Office Action also alleges (page 4, lines 3-5) that Alsmadi et al. teaches “a method of amplifying RNA mixing RT primers with a nucleic acid sample and reverse transcribing to produce cDNA strands each comprising one of the RT primers, wherein each primer comprises a reverse transcription primer portion.” The Office Action relies on the whole document of Alsmadi et al. and specifically col. 35, lines 33-35 of Alsmadi et al. to support this allegation. Applicants submit that this is incorrect. Although, Alsmadi et al. makes a brief mention of reverse transcription, nowhere in Alsmadi et al. is there a disclosure of a method of amplifying RNA by mixing one or more RT primers with a nucleic acid sample and reverse transcribing the RNA to produce cDNA strands each comprising one of the RT primers, wherein each primer comprises a reverse transcription primer portion as claimed. Nowhere in the

disclosure of Alsmadi et al. is there mention of reverse transcription primers, much less reverse transcription primers that comprise a reverse transcription primer portion, nor is there mention of production of cDNA through reverse transcription, wherein the resulting cDNA comprises one of the RT primers.

Thus, the evidence presented in the Office Action to support the present rejection bears no relationship to the claim feature purportedly taught. Accordingly, Alsmadi et al. fails to describe every feature of claims 1, 4-15, 18-29, 31-36, 40-45, 62, 68, 70-72. For at least this reason, Alsmadi et al. fails to anticipate claims 1, 4-15, 18-29, 31-36, 40-45, 62, 68, 70-72. For all of the above reasons, Alsmadi et al. fails to anticipate claims 1, 4-15, 18-29, 31-36, 40-45, 62, 68, 70-71.

Rejections Under 35 U.S.C. § 103

1. Claim 3 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Alsmadi et al. (U.S. Pat. No. 6,573,051 B2), in view of Wei et al. (U.S. 2003/0032014 A1). Applicants respectfully traverse this rejection.

In order for a reference or a combination of references to anticipate a claim or claims, “[f]irst, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.” MPEP § 2143.

The rejection applies Alsmadi et al. in the same way and for the same disclosure for which Alsmadi et al. was applied in the rejection under 35 U.S.C. § 102. For at least the reasons discussed above in connection with the rejection under 35 U.S.C. § 102, Alsmadi et al. fails to disclose or suggest every limitation of claim 3. Wei et al., which is cited for its disclosure of an RT primer that has a poly T, fails to supplement the elements missing from Alsmadi et al. For example, the cited passages of Alsmadi et al. and Wei et al. fail to disclose or suggest hybridizing a capture probe to the cDNA strands produced by reverse transcription of the nucleic

acid sample. Thus, Alsmadi et al. and Wei et al., either alone or in combination, fail to disclose or suggest each and every element of claim 3.

Accordingly, Alsmadi et al. and Wei et al. do not make obvious claim 3. Applicants respectfully request withdrawal of this rejection.

2. Claims 16-17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Alsmadi et al. (U.S. Pat. No. 6,573,051 B2), in view of Lizardi (U.S. 2003/0032024 A1). Applicants respectfully traverse this rejection.

This rejection applies Alsmadi et al. in the same way and for the same disclosure as applied in the rejection under 35 U.S.C. § 102. For at least the reasons discussed above in connection with the rejection under 35 U.S.C. § 102, Alsmadi et al. fails to disclose or suggest every limitation of claims 16-17. Lizardi (which is cited for its disclosure of mixing one or more half probes (gap oligonucleotides) with the cDNA strands wherein each half probe is designed to hybridize a cDNA strand adjacent to where a capture probe hybridizes, ligating the half probes and capture probes hybridized, and after ligation, incubating the capture probes at a temperature of the capture probe but below the melting temperature of the ligated capture probe/half probe) fails to supplement the elements missing from Alsmadi et al. For example, Alsmadi et al. does not disclose or suggest hybridizing a capture probe to the cDNA strands produced by reverse transcription of the nucleic acid sample. Lizardi also fails to disclose or suggest a capture probe as claimed, much less hybridizing sub-probes adjacent to a capture probe on the target cDNA. Thus, neither Alsmadi et al. nor Lizardi disclose or suggest a capture probe let alone a method of hybridizing a capture probe to the cDNA strands produced by reverse transcription of the nucleic acid sample. Thus, Alsmadi et al. and Lizardi, either alone or in combination, fail to disclose or suggest each and every element of the claims.

For at least these reasons, Alsmadi et al. and Lizardi do not make obvious claims 16 and 17. Applicants respectfully request withdrawal of this rejection.

3. Claim 30 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Alsmadi et al. (U.S. Pat. No. 6,573,051 B2), in view of Waggoner et al. (U.S. Pat. No. 6,008,373). Applicants respectfully traverse this rejection.

The rejection applies the Alsmadi et al. in the same way and for the same disclosure as applied in the rejection under 35 U.S.C. § 102. For at least the reasons discussed above in connection with the rejection under 35 U.S.C. § 102, Alsmadi et al. fails to disclose or suggest every limitation of claim 30. Waggoner et al., which is cited for its disclosure of using phycoerythrin as a fluorophore in a detection label on an antibody, fails to supplement the elements missing from Alsmadi et al. For example, neither Alsmadi et al. nor Waggoner et al. disclose or suggest a capture probe let alone a method of hybridizing a capture probe to the cDNA strands produced by reverse transcription of the nucleic acid sample. Therefore, Alsmadi et al. and Waggoner et al., either alone or in combination, fail to disclose or suggest each and every element of the claims.

For at least these reasons, Alsmadi et al. and Waggoner et al. do not make obvious claim 30. Applicants respectfully request withdrawal of this rejection.

4. Claims 2, 48-55, and 69 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Alsmadi et al. (U.S. Pat. No. 6,573,051 B2), in view of Cao et al. (US 2002/0120409 A1). Applicants respectfully traverse this rejection.

This rejection applies the Alsmadi et al. in the same way and for the same disclosure as applied in the rejection under 35 U.S.C. § 102. For at least the reasons discussed above in connection with the rejection under 35 U.S.C. § 102, Alsmadi et al. fails to disclose or suggest every limitation of claims 2, 48-55, and 69. Cao et al., which is cited for its disclosure of fragmenting cDNA in a method to amplify mRNA as well as its disclosure of an RT primer comprising a capture tag of biotin and the cDNA strands having the capture tag, fails to supplement the elements missing from Alsmadi et al. Specifically, neither Alsmadi et al. nor Cao et al. disclose or suggest a capture probe let alone a method of hybridizing a capture probe to the cDNA strands produced by reverse transcription of the nucleic acid sample.

The cited passages of Cao et al. describe a method of fragmenting cDNA and incorporating a "label" into the cDNA, wherein the "label" can be biotin. See Cao et al. claim 1 and paragraphs 0045-0049. The incorporated "label" then serves as a means of detecting the labeled cDNA. See Cao et al., para. 49. It is not clear how these passages of Cao et al. cited in

the Office Action render claims 2, 48-55, and 69 obvious. Specifically, it is not clear how the use of the “label” in Cao et al. for the purposes of detection renders the “capture tags” of claims 2, 48-55, and 69 obvious. Neither Cao et al. nor Alsmadi et al. disclose or suggest the claimed association of fragmented cDNA with a rolling circle amplification primer via a capture tag. Cao et al. and Alsmadi et al. also fail to disclose or suggest the claimed hybridization of a capture probe with fragmented cDNA. Therefore, Alsmadi et al. and Cao et al., either alone or in combination, fail to disclose or suggest each and every element of the claims.

For at least these reasons, Alsmadi et al. and Cao et al. do not make obvious claims 2, 48-55, and 69. Applicants respectfully request withdrawal of this rejection.

5. Claims 56-61 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Alsmadi et al. (U.S. Pat. No. 6,573,051 B2), in view of Shoemaker et al. (U.S. Pat. No. 6,713,257 B2). Applicants respectfully traverse this rejection.

This rejection applies the Alsmadi et al. in the same way and for the same disclosure as applied in the rejection under 35 U.S.C. § 102. For at least the reasons discussed above in connection with the rejection under 35 U.S.C. § 102, Alsmadi et al. fails to disclose or suggest every limitation of claims 56-61. Shoemaker et al., which is cited for its disclosure of using an amino-allyl dUTP in labeling cDNA, fails to supplement the elements missing from Alsmadi et al. For example, neither Alsmadi et al. nor Shoemaker et al. disclose or suggest a capture probe let alone a method of hybridizing a capture probe to the cDNA strands produced by reverse transcription of the nucleic acid sample. Therefore, Alsmadi et al. and Shoemaker et al., either alone or in combination, fail to disclose or suggest each and every element of the claims.

For at least these reasons, Alsmadi et al. and Shoemaker et al. do not make obvious claims 56-61. Applicants respectfully request withdrawal of this rejection.

6. Claim 73 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Alsmadi et al. (U.S. Pat. No. 6,573,051 B2) and Waggoner et al. (U.S. Pat. No. 6,008,373) in view of Cao et al. (US 2002/0120409 A1). Applicants respectfully traverse this rejection.

This rejection applies the Alsmadi et al. in the same way and for the same disclosure as applied in the rejection under 35 U.S.C. § 102. In addition, the Office action applies Alsmadi et

al., Waggoner et al. and Cao et al. in the same way and for the same disclosures as applied above in the rejections under 35 U.S.C. § 103. For at least the reasons discussed above in connection with the rejections under 35 U.S.C. §§ 102 and 103, Alsmadi et al., Waggoner et al. and Cao et al fail to disclose or suggest every limitation of claim 73. The Office Action has failed to point to any further evidence, outside of what each of the cited patents and application were cited for earlier, to support a disclosure of a capture probe, let alone a method of hybridizing a capture probe to the cDNA strands produced by reverse transcription of the nucleic acid sample. There is no teaching or suggestion in Alsmadi et al., Waggoner et al., or Cao et al to use capture probes in the manner claimed, namely hybridizing a capture probe to the cDNA strands produced by reverse transcription of the nucleic acid sample. Therefore, Alsmadi et al., Waggoner et al. and Cao et al., either alone or in combination, fail to disclose each and every element of the claims.

For at least these reasons, Alsmadi et al. and Waggoner et al. in view of Cao et al. do not make obvious claim 73. Applicants respectfully request withdrawal of this rejection.

Pursuant to the above amendments and remarks, reconsideration and allowance of the pending application is believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issue.

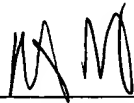
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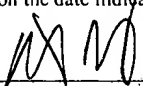


Robert A Hodges
Registration No. 41,074

NEEDLE & ROSENBERG, P.C.
Customer Number 23859
(678) 420-9300
(678) 420-9301 (fax)

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